



Nutrition & Supplement Facts Label Proposed Rule

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Proposed Rules Issued

- ***Revision of the Nutrition and Supplement Facts Label***
 - *Proposes updates to label content (mandated nutrients, daily values)*
 - *Proposes changes to format*
- **Serving Sizes, Dual-Column Labeling, Reference Amounts Customarily Consumed, Breath Mints**
 - Proposes revisions for serving size requirements based on updated consumption data
 - Proposes criteria for labeling certain package sizes



Key Proposed Changes

- No longer permit “Calories from fat”
- Mandatory listing of vitamins and minerals
- Mandatory listing of added sugars
- Updated Daily Values for vitamins and minerals
- Definition for dietary fiber
- Daily Values for subpopulations
- Record Keeping



Calories

- *No longer permit “Calories from fat”*
- Retain 2,000 calories as the reference energy intake level for setting Daily Values (DVs) that are based on calories (e.g., fat and dietary fiber)



Caloric Value of Nutrients

- Dietary fiber
 - Retain zero kcal/g for insoluble fiber
 - Change the caloric value of soluble fiber from 4 to 2 *kcal/g*
- Sugar alcohols
 - *Isomalt (2.0 kcal/g), lactitol (2.0 kcal/g), xylitol (2.4 kcal/g), maltitol (2.1 kcal/g), sorbitol (2.6 kcal/g), hydrogenated starch hydrolysates (3.0 kcal/g), mannitol (1.6 kcal/g)*



General Factors Considered for Labeling of Non-statutory Nutrients

- 1) Quantitative intake recommendations for establishing DVs (DRIs or Dietary Guidelines for Americans)

AND

- 2) Public health significance

OR

Other Considerations (e.g. *trans* fat and added sugars)

Statutory nutrients - Total fat, saturated fat, cholesterol, sodium, total carbohydrate, sugars, dietary fiber, and total protein



Public Health Significance

- Well-established scientific evidence linking nutrient & chronic disease risk, a health-related condition, or physiological endpoint
- Nutrients for which the RDA* or AI* are based on chronic disease risk, a health-related condition, or physiological endpoint

*RDA= Recommended Dietary Allowance; AI = Adequate Intake



Public Health Significance (cont.)

- Nutrient deficiency with clinical significance
- Inadequate or excess intake of the nutrient and substantial prevalence exists in the general U. S. population of the chronic disease, or health-related or physiological endpoint linked to the particular nutrient



Nutrients of Public Health Significance

- Currently Calcium, Iron, and Vitamins A and C are required on the label
- Based on new analyses to assess nutrient adequacy and other factors
 - *Vitamins A and C no longer required*
 - *Vitamin D and Potassium would be required*
 - Calcium and Iron would continue to be required



Nutrients of Public Health Significance (cont.)

- *Also proposing that the absolute amounts for all vitamins and minerals be listed on the label, similar to other nutrients (e.g., sodium and total fat)*



Added Sugars

- Current label does not provide information on “added sugars.”
- 2010 DGA recommends reducing the intake of calories from solid fats and added sugars
 - For most people, no more than 5-15% of total calories from solid fats and added sugars can be reasonably consumed to meet nutrient needs within calorie limits.
 - Americans on average eat 16% of their total calories from added sugars



Defining Added Sugars

- Any “sugar” added during the processing of foods or consumed separately (sugars, syrups, naturally-occurring sugars that are isolated from a whole food and concentrated so that sugar is the primary component [e.g., fruit juice concentrates], other caloric sweeteners)



Justification for Mandating Added Sugars

- Reducing calories from added sugars:
 - Reduces extra calories consumed by Americans
 - Increases intake of nutrient-dense foods without exceeding total calorie needs
- Can assist consumers in maintaining healthy dietary practices consistent with the 2010 DGAs
 - Identify products with added sugars
 - Compare products for amount of “added sugars”



Daily Values for Vitamins and Minerals

- Propose to continue using the RDA, when available, for setting a DV
- *Propose to use the AI for setting a DV*
- Propose to continue to use the population-coverage approach for setting the DV



Examples of Changes to the Daily Values

- Dietary fiber – 25 to 28 *g*
- Sodium – 2,400 to 2,300 *mg*
- Potassium – 3,500 to 4,700 *mg*
- Calcium- 1,000 to 1,300 *mg*
- Vitamin D - 400 IUs (10 μ g) to 20 *ug*
- *No DV for Added Sugar*



Units of Measure

- *Propose to no longer use International Units for vitamins A, D and E but rather $\mu\text{g}/\text{mg}$:*
 - *Vitamin A (μg RAE)*
 - *Vitamin D (μg)*
 - *Vitamin E (mg as α -tocopherol)*
- *Folate – Dietary Folate Equivalents (μg DFE)*



Current Dietary Fiber Requirements

- No definition of dietary fiber
- Isolated and synthetic nondigestible carbohydrates without beneficial health effects
 - Can be added to foods and quantified as dietary fiber
- Isolated or synthetic nondigestible carbohydrates with beneficial health effects
 - Can be added to foods but not quantified using the current available analytical methods



Proposed Dietary Fiber Definition

- *Non-digestible carbohydrates (≥ 3 monomeric units) and lignin that are intrinsic and intact in plants*
- *Added (isolated or synthetic) non-digestible carbohydrates (≥ 3 monomeric units) that have been determined by FDA to have a physiological benefit*



Declaration of Dietary Fiber

- *Health claim petition*
 - *Barley β -fiber that is added to foods would meet the definition of dietary fiber since it has been authorized for a health claim (21 CFR 101.81)*
- *Citizen petition*
 - *We intend to issue guidance to industry on citizen petitions to substantiate physiological effects of added non-digestible carbohydrates that are beneficial to human health*



Nutrition Facts Labels for Subpopulations

- Proposed age groups changed from less than 2 years and 2 through 3 years to:
 - *7 through 12 months (older infants)*
 - *1 through 3 years (young children)*
- *DVs established for pregnant/lactating women for the same nutrients as established for the general population using coverage RDA/AI*



Labeling of Foods for Older Infants

- *Mandatory declaration of percent DV for total fat and total carbohydrate*
- *The DVs for total fat, total carbohydrate and protein are based on the AI or RDA for older infants.*
- *The DVs for vitamins and minerals are based on the RDA/AI for infants 7–12 months of age*



Labeling of Foods for Young Children

- *The DVs are based on the RDAs/AIs for children 1 - 3 years of age for the same nutrients set for the general population*
- *1,000 calories is used to set DVs that are based on calories (e.g., fat and dietary fiber)*



Record Keeping

- *Record keeping would be required for foods that contain:*
 - *both natural and added sugars*
 - *both folate and folic acid*
 - *both dietary fiber and added nondigestible carbohydrates that do not meet the definition of dietary fiber*
 - *both synthetic and natural vitamin E*